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Aptalis Pharma US Inc. and
Aptalis Pharma Canada Inc.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

APTALIS PHARMA US INC., and
APTALIS PHARMA CANADA INC.,

Plaintiffs,

vs.

MYLAN PHARMACEUTICALS, INC., and
MYLAN INC.,

Defendants.

Civil Action No.13-4158 (MLC) (LHG)

FIRST AMENDED COMPLAINT

Plaintiffs Aptalis Pharma US Inc. and Aptalis Pharma Canada Inc. (herein referred to separately or collectively as "Aptalis"), by way of Complaint against Mylan Inc. and Mylan Pharmaceuticals, Inc. (herein referred to collectively as "Mylan"), allege as follows:

NATURE OF THE ACTION

This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the filing by Mylan of an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of CANASA® prior to the expiration of U.S. Patent No. 7,541,384 ("the '384 patent"), U.S. Patent No. 8,217,083 ("the '083 patent") and U. S. Patent No. 8,436,051 ("the '051 patent").

PARTIES

1. Aptalis Pharma US Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 100 Somerset Corporate Boulevard, Suite 2000, Bridgewater, New Jersey 08807.

2. Aptalis Pharma Canada Inc. is a corporation organized and existing under the Canada Business Corporations Act, having a principal place of business at 597 Laurier Boulevard, Mont-Saint-Hilaire, Quebec, J3H 6C4, Canada.

3. Mylan Inc. is a corporation organized and existing under the laws of the State of Pennsylvania, having a principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317.

4. Mylan Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of West Virginia, having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

5. Mylan Pharmaceuticals, Inc. is a wholly owned subsidiary of Mylan Inc.

6. Upon information and belief, Mylan Pharmaceuticals, Inc. acts at the direction of, under the control of, and for the benefit of Mylan Inc. and is controlled and/or dominated by Mylan Inc.

JURISDICTION AND VENUE

7. This action arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, including 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338.

8. Mylan Inc. is subject to personal jurisdiction within this District because, among other reasons, it regularly and systematically conducts business in New Jersey, and because it has purposefully directed its activities at New Jersey and purposefully availed itself of the laws of New Jersey through, among other

things, the marketing, sales and/or distribution of pharmaceutical products in this judicial district, either by itself or through one or more of its wholly owned subsidiaries, including Mylan Pharmaceuticals, Inc.

9. Mylan Pharmaceuticals, Inc. is subject to personal jurisdiction within this District because, among other reasons, it regularly and systematically conducts business in New Jersey, and because it has purposefully directed its activities at New Jersey and purposefully availed itself of the laws of New Jersey through, among other things, the marketing, sales and/or distribution of pharmaceutical products in this judicial district. On information and belief, Mylan Pharmaceuticals, Inc. derives substantial revenue from articles used and consumed in this judicial district. On information and belief, Mylan Pharmaceuticals, Inc. markets products through distributors with retail branch locations in this district.

10. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b), 1391(c), and/or 28 U.S.C. § 1400(b).

PATENTS-IN-SUIT

11. On information and belief, Mylan submitted an ANDA ("its ANDA" or "Mylan's ANDA") with the FDA, pursuant to 21 U.S.C. § 355(j), that seeks approval to, among other things, market a generic version of Aptalis' mesalamine rectal suppository product, CANASA®.

12. Aptalis holds an approved New Drug Application ("NDA"), No. 021252, which was approved by the FDA for, among other things, the manufacture and sale of CANASA®. CANASA® is a mesalamine rectal suppository and is approved for the treatment of active ulcerative proctitis.

13. United States Patent No. 7,541,384 ("the '384 patent") (attached hereto as Exhibit A), titled "Mesalamine Suppository," was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on June 2, 2009.

14. United States Patent No. 8,217,083 ("the '083 patent") (attached hereto as Exhibit B), titled "Mesalamine Suppository," was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on July 10, 2012.

15. United States Patent No. 8,436,051 ("the '051 patent") (attached hereto as Exhibit C), titled "Mesalamine Suppository," was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on May 7, 2013.

16. Aptalis owns all rights, title, and interest in and to the '384, '083 and '051 patents, including the right to sue and obtain relief for past, present, and future patent infringement. Aptalis Pharma Canada Inc. is assignee of the '384, '083 and '051 patents. Aptalis Pharma US Inc. is the exclusive licensee of the '384, '083 and '051 patents and the holder of NDA No. 021252 for mesalamine rectal suppositories, which it sells under the trade name CANASA®.

17. The '083 and '051 patents were submitted to the FDA for listing in the FDA's publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "Orange Book") for the CANASA® product.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 7,541,384

18. Aptalis repeats and incorporates by reference, as if fully set forth herein, the allegations contained in paragraphs 1 through 17 above.

19. Mylan prepared, submitted, and filed its ANDA with the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (codified at 21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, use, sale, offer for sale, marketing and/or importation into the United States of a generic mesalamine rectal suppository (Mylan's "Proposed Product") before the expiration of the '384 patent.

20. Mylan's filing of an ANDA for purposes of obtaining FDA approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale or inducement thereof, of its Proposed Product before the expiration of the '384 patent is an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

21. On information and belief, Mylan plans, intends to, and will commercially make, use, offer to sell, and/or sell the its Proposed Product within the United States, or import its Proposed Product into the United States during the

term of the '384 patent, after its ANDA is approved, which would further infringe the '384 patent.

22. Mylan's commercial manufacture, use, sale, offer for sale, marketing and/or importation into the United States of its Proposed Product, as set forth in its ANDA, will infringe one or more claims of the '384 patent under, for example, 35 U.S.C. §271(a), 35 U.S.C. §271(b), and/or 35 U.S.C. §271(c).

23. If Mylan is permitted to manufacture, use, sell, offer for sale, market and/or import its Proposed Product into the United States, Aptalis will suffer substantial and irreparable harm for which it has no adequate remedy at law, unless Mylan is enjoined by this Court.

COUNT II: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 7,541,384

24. Aptalis repeats and incorporates by reference, as if fully set forth herein, the allegations contained in paragraphs 1 through 23 above.

25. On information and belief, Mylan has taken significant and concrete steps toward infringement of the '384 patent under, for example, 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), including by submitting its ANDA for FDA approval of Mylan's Proposed Product, and by preparing to market and sell its Proposed Product.

26. If Mylan is permitted to manufacture, use, sell, offer for sale, market and/or import its Proposed Product into the United States, Aptalis will suffer substantial and irreparable harm for which it has no adequate remedy at law, unless Mylan is enjoined by this Court.

COUNT III: INFRINGEMENT OF U.S. PATENT NO. 8,217,083

27. Aptalis repeats and incorporates by reference, as if fully set forth herein, the allegations contained in paragraphs 1 through 26 above.

28. Mylan prepared, submitted, and filed its ANDA with the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (codified at 21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, use, sale, offer for sale, marketing and/or importation into the United States of a generic mesalamine rectal suppository (Mylan's "Proposed Product") before the expiration of the '083 patent.

29. Mylan has included in its ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "paragraph IV certification") that, in its opinion and to the best of its knowledge, the '083 patent is invalid, unenforceable and/or not infringed by Mylan's Proposed Product.

30. Mylan sent a notice letter to Aptalis in which Mylan represented that it had filed an ANDA for its Proposed Product, including its paragraph IV

certification with respect to the '083 patent, and that it sought approval of its ANDA prior to expiration of the '083 patent.

31. Mylan's filing of an ANDA for purposes of obtaining FDA approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale or inducement thereof, of its Proposed Product before the expiration of the '083 patent is an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

32. On information and belief, Mylan plans, intends to, and will commercially make, use, offer to sell, and/or sell the its Proposed Product within the United States, or import its Proposed Product into the United States during the term of the '083 patent, after its ANDA is approved, which would further infringe the '083 patent.

33. Mylan's commercial manufacture, use, sale, offer for sale, marketing and/or importation into the United States of its Proposed Product, as set forth in its ANDA, will infringe one or more claims of the '083 patent under, for example, 35 U.S.C. §271(a), 35 U.S.C. §271(b), and/or 35 U.S.C. §271(c).

34. If Mylan is permitted to manufacture, use, sell, offer for sale, market and/or import its Proposed Product into the United States, Aptalis will suffer substantial and irreparable harm for which it has no adequate remedy at law, unless Mylan is enjoined by this Court.

COUNT IV: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,217,083

35. Aptalis repeats and incorporates by reference, as if fully set forth herein, the allegations contained in paragraphs 1 through 34 above.

36. On information and belief, Mylan has taken significant and concrete steps toward infringement of the '083 patent under, for example, 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), including by submitting its ANDA for FDA approval of Mylan's Proposed Product, and by preparing to market and sell its Proposed Product.

37. If Mylan is permitted to manufacture, use, sell, offer for sale, market and/or import its Proposed Product into the United States, Aptalis will suffer substantial and irreparable harm for which it has no adequate remedy at law, unless Mylan is enjoined by this Court.

COUNT V: INFRINGEMENT OF U.S. PATENT NO. 8,436,051

38. Aptalis repeats and incorporates by reference, as if fully set forth herein, the allegations contained in paragraphs 1 through 37 above.

39. Mylan prepared, submitted, and filed its ANDA with the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (codified at 21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, use, sale, offer for sale, marketing and/or importation into the United States of a generic

mesalamine rectal suppository (Mylan's "Proposed Product") before the expiration of the '051 patent.

40. Mylan has included in its ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "paragraph IV certification") that, in its opinion and to the best of its knowledge, the '051 patent is invalid, unenforceable and/or not infringed by Mylan's Proposed Product.

41. Mylan sent a notice letter to Aptalis in which Mylan represented that it had filed an ANDA for its Proposed Product, including its paragraph IV certification with respect to the '051 patent, and that it sought approval of its ANDA prior to expiration of the '051 patent.

42. Mylan's filing of an ANDA for purposes of obtaining FDA approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale or inducement thereof, of its Proposed Product before the expiration of the '051 patent is an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

43. On information and belief, Mylan plans, intends to, and will commercially make, use, offer to sell, and/or sell its Proposed Product within the United States, or import its Proposed Product into the United States during the term of the '051 patent, after its ANDA is approved, which would further infringe the '051 patent.

44. Mylan's commercial manufacture, use, sale, offer for sale, marketing and/or importation into the United States of its Proposed Product, as set forth in its ANDA, will infringe one or more claims of the '051 patent under, for example, 35 U.S.C. §271(a), 35 U.S.C. §271(b), and/or 35 U.S.C. §271(c).

45. If Mylan is permitted to manufacture, use, sell, offer for sale, market and/or import its Proposed Product into the United States, Aptalis will suffer substantial and irreparable harm for which it has no adequate remedy at law, unless Mylan is enjoined by this Court.

COUNT VI: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,436,051

46. Aptalis repeats and incorporates by reference, as if fully set forth herein, the allegations contained in paragraphs 1 through 45 above.

47. On information and belief, Mylan has taken significant and concrete steps toward infringement of the '051 patent under, for example, 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), including by submitting its ANDA for FDA approval, and by preparing to market and sell its Proposed Product.

48. If Mylan is permitted to manufacture, use, sell, offer for sale, market and/or import its Proposed Product into the United States, Aptalis will suffer

substantial and irreparable harm for which it has no adequate remedy at law, unless Mylan is enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Aptalis respectfully requests the following relief:

A. Judgment that Mylan has infringed or will infringe one or more claims of the '384, '083 and/or '051 patents;

B. Judgment that the claims of the '384, '083 and/or '051 patents are valid and enforceable;

C. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Mylan's ANDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the expiration dates of the '384, '083 and '051 patents, including any extensions;

D. A declaratory judgment that Mylan would infringe one or more claims of the '384, '083 and/or '051 patents if it manufactures, uses, sells, offers to sell, markets and/or imports into the United States its Proposed Product prior to the expiration of the '384, '083 and '051 patents, including any extensions;

E. Pursuant to 35 U.S.C. § 271(e)(4)(B), an injunction restraining and enjoining Mylan and its officers, agents, attorneys and employees, and those acting in privity or concert with Mylan, from engaging in the commercial manufacture, use, offer for sale, sale, marketing and/or importation into the

United States, of Mylan's Proposed Product as claimed in one or more claims of the '384, '083 and/or '051 patents, until the expiration dates of the '384, '083 and '051 patents, including any extensions;

F. If Mylan commercially makes, uses, sells, or offers to sell the its Proposed Product within the United States, or imports its Proposed Product into the United States, prior to the expiration of any one of the '384, '083 and '051 patents, including any extensions, that Aptalis be awarded monetary damages for those infringing acts to the fullest extent allowed by law, and be awarded prejudgment interest based on those monetary damages;

G. Judgment that this is an exceptional case and that Aptalis is entitled to its reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

H. The costs and expenses of this action; and

I. Such other and further relief as the Court may deem just and proper.

Dated: November 6, 2013 Respectfully submitted,

s/ Sheila F. McShane
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